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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,054	10/15/2001	Nordine Cheikh	16517.256/38-21(15094)C	3580

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EXAMINER	
ZEMAN, MARY K	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/19/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,054	CHEIKH ET AL.	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *3-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-2 and SEQ ID NO: 5 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that there is no serious burden in the search and examination of more than one patentably distinct group, and that the search and examination of more than one sequence would not pose a serious burden upon the office. This is not found persuasive because as set forth in the restriction requirement, each group is separate and patentably distinct, each having search and examination concerns that are not shared by each group. I regards to the number of sequences, in view of limited office resources, a single sequence election is appropriate.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-7 and all other sequences are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

The claims **must** be amended to reflect the elected invention.

Information Disclosure Statement

The IDS filed with the application has been entered and considered. An initialed copy of the form is included with this action.

Priority

This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 09/227,586, filed 01/08/1999." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

The current priority information in the specification (preliminary amendment A) fails to set forth how this application is related to the various non-provisional applications cited.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See, for example, pages 14, 16 and 48.

35 U.S.C. 112, Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 5 which corresponds to a short fragment of a cDNA asserted to encode a species of adenine phosphoribosyltransferase. This sequence is 440 base pairs in length, *and comprises at least 10% or about 40 unknown residues*. Claims limited to isolated polynucleotides consisting of SEQ ID NO: 5 would meet the written description provisions of 35 USC 112, first paragraph. However, claims 1-2 are directed to encompass gene sequences, open reading frames, fragments, sequences that hybridize to SEQ ID NO: 5, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. The entire reading frame or full length cDNA for the enzyme is not disclosed. The short sequence of SEQ ID NO: 5 is

insufficient to be the entire reading frame of the enzyme, and this sequence contains a significant amount of unknown residues, therefore no species of the full enzyme are disclosed in the specification. The specification does not disclose what function or activity is encoded in any of the *short* EST sequences. As set forth herein, these sequences are too small to encode the entire enzyme such that one of skill in the art would be able to determine if other sequences could encode the same asserted functions. The specification does not identify which portions of the full length gene these elected sequences correspond to, nor does the specification disclose if any shorter sequences would be expected to encode any function of the enzyme. One of skill in the art would not be able to determine what fragments, and mutants or alleles would fall within the scope of the claims, or even what the unknown residues should be in the full length sequence.

None of these sequences encompassed by the claims meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 5, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 5 but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to isolated polynucleotides encoding maize or soybean enzymes, particularly adenine phosphoribosyltransferase, (APRT) and fragments thereof. The elected sequence corresponding to the elected enzyme is SEQ ID NO: 5. SEQ ID NO: 5 is 440 base pairs in length with approximately 10% unknown residues. Claims 1 and 2 set forth that the isolated polynucleotides encode maize or soybean APRT enzymes.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must make or identify isolated polynucleotides which encode maize or soybean APRT proteins, which also hybridize to or comprise the short elected sequence (less than 450 base pairs, with approximately 10% unknown residues). For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The specification provides guidance for making the particular short EST sequences which were elected. The specification provides only one function for the APRT protein, which is to catalyze the conversion of iP to [9R-5'P]iP (page 7). The specification indicates that the disclosed sequences are *partial* sequences, which show various levels of homology to known APRT enzymes, but does not indicate where in the APRT gene the homology for each sequence lies, or whether the fragments encode an

active fragment of the enzyme. The elected sequence is only a partial sequence, and therefore does not comprise the entire coding region of the enzyme. The elected sequence comprises a significant number of unknown residues "n". The specification is silent with regard to the unknown residues in the elected sequence. There is no guidance as to how to resolve these unknown residues, nor is there any information as to how they could impact the function, or relatedness of sequences with the elected sequence.

c) The specification provides working examples of making cDNA libraries which comprise short expressed sequence tags of plant DNA, and examples of the specifically elected claims only. EST-type sequences are generally about 300-500 bp in length.

d) The invention is drawn to isolated polynucleotides which encode APRT enzymes.

e) As previously stated, Moffat et al. disclose an APRT gene from *A. thaliana.* The APRT gene known in the plant *A. Thaliana,* was shown by Moffat et al. to comprise 5 introns, and be about 1750 bp in length (Figure 2, Moffat et al. 1994 Gene vol 143 pages 211-216, PTO-1449). This is a much longer polynucleotide than those disclosed, and elected and one of skill in the art would not be able to predict what additional sequences are required, beyond those provided. One of skill in the art would have to provide about 1200 additional base pairs of sequence, and resolve the unknown residues in SEQ ID NO: 5 before being able to determine whether a sequence *may* in fact encode the claimed enzyme. The 5,770,718 patent to Moffat et al. discusses known APRT encoding sequences and notes that the DNA sequences encoding APRT genes of differing known genes are *lacking in sequence similarity*, and that previous hybridization experiments to identify APRT encoding sequences had been unsuccessful (col 3-4). This indicates that one of skill in the art could not look to other known APRT genes for guidance as to what other sequences would be required in order to make the elected sequence capable of encoding an APRT gene as required.

f) The skill of those in the art of molecular biology is high.

g) The prior art predicts that sequences which encode APRT enzymes are about 1700 bp in length, much longer than the disclosed polynucleotides, and that new APRT encoding sequences are unlikely to be significantly similar to known sequences.

h) The claims are broad because they are drawn to polynucleotides encoding the full length genes encoding the enzymes. The specification does not disclose these sequences nor do they indicate which portions of the enzymes are encoded by the disclosed sequences. No open reading frames are identified such that they could be compared with any known proteins. Further, it would require undue experimentation for one of ordinary skill in the art to determine what fragments of an APRT enzyme sequence would retain APRT activity, or retain the character of an APRT protein. The specification, as filed, does not identify any enzymatically active fragments of the APRT protein, nor does it indicate how much of the sequence is required to considered an APRT protein. A single amino acid is a fragment of the protein, but does not retain any of the biochemical, enzymatic, or structural elements which identify APRT proteins.

The skilled practitioner would first turn to the instant specification for guidance to practice methods of making or identifying full length polynucleotides encoding APRT enzymes. However, the instant specification does not provide specific guidance to practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art shows that the sequences are quite long, comprising a variety of introns and exons such that one could not predict the additional sequences required to produce the full length enzymes. Also, the prior art notes that various known APRT genes are generally lacking in sequence similarity. Finally, said practitioner would turn to trial and error experimentation to determine the full length sequences required, and to resolve the significant unknown residues in the elected sequence. Such represents undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 are vague and indefinite as they recite non-elected embodiments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Moffatt (USP 5,770,718).

Claims 1 and 2 are drawn to isolated polynucleotides encoding an APRT (adenine phosphoribosyltransferase) protein, or fragments thereof, from maize or soybean. Claim 1 does not set forth any particular sequence. The specifically elected sequence from claim 2 is SEQ ID NO: 5.

Moffatt (USP 5,770,718; PTO-1449) discloses isolated polynucleotides encoding an APRT from *A. Thaliana*. The sequence of Moffatt has significant homologies to the elected polynucleotide sequence, with stretches of complete identity. These stretches would encode fragments of the APRT from maize or soybean, as the encoding sequences are identical.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Moffatt et al. (Moffat et al. 1994 Gene vol 143 pages 211-216, PTO-1449).

Moffatt et al. (Moffat et al. 1994 Gene vol 143 pages 211-216, PTO-1449) discloses isolated polynucleotides encoding an APRT from *A. Thaliana*. Moffatt identifies these sequences as Genbank Records Locus: ATHAPT1A or Accession Number: L19637 (Submitted on PTO-1449). The sequence of Moffatt et al. has significant homologies to the elected polynucleotide sequence, with stretches of complete

identity. These stretches would encode fragments of the APRT from maize or soybean, as the encoding sequences are identical.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
12/14/02

MARY K. ZEMAN
PRIMARY EXAMINER
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